REMARKS

I. Preliminary Remarks

In the Office Action, Claims 1 and 3-13 are pending and under examination. Claims 14-51 are withdrawn in response to a requirement for restriction, with traverse and without prejudice, in an effort to favorably advance prosecution of the present application. Applicants reserve the right to petition for rejoinder should the circumstances allow, or to pursue the subject matter of the withdrawn claims in divisional applications.

After entry of this paper, Claims 5, 8, 12, and 13 are original. Claims 1, 7, 10, and 11 are currently amended. Claims 3 and 4 are previously presented. Claims 2, 6, and 9 are canceled. Thus, Claims 1, 3-5, 7-8, and 10-13 are under consideration. Support for the amendments is found throughout the specification. The amendments do not include new matter. In this response, Applicants address each of the Examiner's rejections. Reconsideration and withdrawal of the rejections are solicited for the reasons set out below. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

This Response is timely filed. The USPTO is given authorization to charge Deposit Account No. 16-1445 for any fees necessary with the submission of this Response.

II. Patentability Arguments.

A. The Written Description Rejection Under 35 USC §112 First Paragraph May be Properly Withdrawn.

To satisfy the requirements under 35 U.S.C. §112, first paragraph, the application as filed must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991); *see* also M.P.E.P. §2163 (I). The initial burden of establishing a *prima facie* case of lack of written descriptive support is on the Office. M.P.E.P. §2163 (II). There is a strong presumption that an adequate written description of the claimed invention (i.e., the claims) is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *see* also M.P.E.P. §2163 (I)(A).

Claims 1 and 3-13 are rejected under 35 U.S.C. 112, first paragraph, as containing "subject matter which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." The Examiner states that "Claim 1 has been amended to recite that the p68 antigen 'lacks the signal sequence'. However, support for this new language/limitation cannot be found anywhere in the originally filed specification. The sequence listing also fails to describe which amino acids represent the signal sequence." Applicants respectfully traverse this rejection.

As stated in the M.P.E.P. § 2163:

> [a]n applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. *Enzo Biochem,* 323 F.3d 956, 964 (Fed. Cir. 2002).

It is well settled that the definiteness of a claim is not judged in a vacuum. Instead the claim must be viewed in the context of the disclosure of the application from which it is derived. The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1 USPQ2d 1081 (Fed. Cir. 1986). See also BJ Services Co. v. Halliburton Energy Services, Inc. 338 F.3d 1368, 1372, 67 USPQ2d 1692, (Fed. Cir. 2003): "The question becomes whether one of ordinary skill in the art would understand what is claimed when the claim is read in light of the specification." Given the explicit teachings of the specification referred to above with respect to the sequence, the Applicants submit that one skilled in the art, upon reading the specification, would clearly be able to understand the phrase "lacks the signal sequence".

Paragraph 0084 states that "The experimental vaccine antigen was a recombinant p68 outer membrane protein (SEQ ID NO. 1)..." SEQ ID NO. 1 clearly lacks the signal sequence. One of ordinary skill in the art would be able to verify this easily by performing a BLAST search against the Genbank database. From the BLAST search, they would know that SEQ ID NO. 1 was missing a portion of the sequence and would know that the missing portion was the signal sequence.

Claims 6 and 9 have been canceled, thus rendering this rejection moot in regard to these claims.

In view of the foregoing, Applicants respectfully submit that one skilled in the art can make and use the claimed vaccine without undue experimentation. There is written description support for claims 1 and 3-5, 7-8, and 10-13. The rejection of claims 1 and 3-13 under 35 U.S.C. §112, first paragraph, is thus overcome. Withdrawal of this rejection is respectfully requested.

B. The Anticipation Rejections under 35 U.S.C. §102(b) May Properly Be Withdrawn.

A patent is invalid for anticipation under 35 U.S.C. 102(b) if a single prior art reference identically discloses each and every limitation of the invention as set forth in the claims. (Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987)). The prior publication must disclose in an enabling manner the invention that is in question. The exclusion of a claimed element, no matter how insubstantial or obvious, from a reference is enough to negate anticipation. (Connell v. Sears, Roebuck & Co., 220 U.S.P.Q. 193, 1098 (Fed. Cir. 1983)). Applicant respectfully submits that these criteria are not met in the Examiner's rejection. The claims, therefore, are not anticipated by the references.

1. The Anticipation Rejection of Claims 1, 3, 4, 5, and 9 under 35 U.S.C. §102(b) May Properly Be Withdrawn.

Claims 1, 3, 4, 5, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Charles, et al., (WO 92/17587). Applicants respectfully traverse this rejection.

SEQ ID NO 1 is recombinant p68 expressed without the signal sequence. Charles only cloned, and therefore only teaches and enables, recombinant expression of the full-length p68 (see p. 12, lines 12-14) including the 5' portion encoding the signal sequence (see Results and Fig. 1), which is clearly distinct and different from the present invention.

The Applicants have enabled the cloning and expression of p68 lacking its signal sequence, which resulted in recombinant p68 without a signal sequence to be expressed inside the *E. coli* host cell. The recombinant protein was readily purified from the host cell, adjuvanted, and proven to be efficacious as a vaccine.

Claim 1 has been amended to state "wherein the adjuvant comprises saponin and a surfactant". Charles, et al., do not disclose a vaccine composition comprising recombinantly produced p68 antigen which lacks the signal sequence, and an adjuvant comprising a saponin and a surfactant.

Thus, Charles, et al., do not disclose each and every element of Claim 1 in an enabling manner. Claims 3-5 depend from Claim 1. These claims further delineate the vaccine composition of Claim 1; they embody all the elements of Claim 1. Accordingly, the subject matter of Claims 1 and 3-5 is not anticipated by Charles. Claim 9 is canceled rendering this rejection of this claim moot. Based on the remarks presented herein, the rejection of Claims 1, 3-5, and 9 under 35 U.S.C. §102(b) is overcome. Withdrawal of the rejection is therefore respectfully requested.

2. The Anticipation Rejection of Claims 1, 3, 4, and 5 under 35 U.S.C. §102(b) May Properly Be Withdrawn.

Claims 1, 3, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Montaraz et al (Infection and Immunity, 1985, 47: 744-751). Applicants respectfully traverse this rejection.

Claim 1 is directed to a vaccine composition comprising a *Bordetella bronchiseptica* p68 antigen, wherein the antigen is produced recombinantly, and an adjuvant wherein the adjuvant comprises a saponin and a surfactant. Montaraz, et al., used native p68 purified from *B. bronchiseptica* cells (see Materials and Methods section beginning on page 744); they did not use recombinantly produced p68 as is done in the instant application (see amended claim 1). Montaraz, et al., do not disclose a vaccine composition comprising recombinantly produced p68 antigen which lacks the signal sequence, and an adjuvant comprising a saponin and a surfactant. While the amino acid sequence for p68 may be inherent in what is set forth in Montaraz, the nucleotide sequence is not, because of degeneracy of the genetic code. Also, native protein is separate and distinct from recombinant protein.

Thus, Montaraz, et al., do not disclose each and every element of Claim 1 in an enabling manner. Claims 3-5 depend from Claim 1. These claims further delineate the vaccine composition of Claim 1; they embody all the elements of Claim 1. Accordingly, the subject matter of Claims 1 and 3-5 is not anticipated by Montaraz. Based on the remarks presented herein, the rejection of Claims 1, and 3-5 under 35 U.S.C. §102(b) is overcome. Withdrawal of the rejection is therefore respectfully requested.

3. The Anticipation Rejection of Claims 1, 3, 4, and 5 under 35 U.S.C. §102(b) May Properly Be Withdrawn.

Claims 1, 3, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Novotny et al (Infection and Immunity, 1985, 50: 190-198). Applicants respectfully traverse this rejection.

Claim 1 is directed to a vaccine composition comprising a *Bordetella bronchiseptica* p68 antigen, wherein the antigen is produced recombinantly, and an adjuvant wherein the adjuvant comprises a saponin and a surfactant. Novotny, et al., used whole cell preparations not compositions comprising purified p68, wherein the p68 was produced recombinantly. Novotny, et al., do not disclose a vaccine composition comprising recombinantly produced p68 antigen which lacks the signal sequence, and an adjuvant comprising a saponin and a surfactant. While the amino acid sequence for p68 may be inherent in what is set forth in Novotny, the nucleotide sequence is not, because of degeneracy of the genetic code. Also, native protein is separate and distinct from recombinant protein.

Thus, Novotny, et al., do not disclose each and every element of Claim 1 in an enabling manner. Claims 3-5 depend from Claim 1. These claims further delineate the vaccine composition of Claim 1; they embody all the elements of Claim 1. Accordingly, the subject matter of Claims 1 and 3-5 is not anticipated by Novotny. Based on the remarks presented herein, the rejection of Claims 1, and 3-5 under 35 U.S.C. §102(b) is overcome. Withdrawal of the rejection is therefore respectfully requested.

C. The Obviousness Rejection of Claims 6-8 and 10-13 under 35 U.S.C. §103(a) May Be Properly Withdrawn.

As stated in the MPEP (§2141), to support an obviousness rejection, four basic criteria must be met. These are (A) The claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) Reasonable expectation of success is the standard with which obviousness is determined. Clearly for prior art to render an invention obvious, it must render obvious the whole invention and not merely some part of the invention (*In re Antonie* 559 F.2d 618, 620, 195 USPQ 6,8 (CCPA 1997)). The prior art must also be considered as a whole including parts that teach away from Applicant's invention. Applicants respectfully submit that these criteria are not met in the Examiner's rejection.

Claims 6-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Charles et al (WO 92/17587), Montaraz et al (Infection and Immunity, 1985, 47: 744-751) or by Novotny et al (Infection and Immunity, 1985, 50: 190-198) in view of Akzo et al (EP 0 535 740 A1) and Garcon et al (WO 96/33739) and further in view of Acree et al (US Patent No. 4,567,042). Applicants respectfully traverse this rejection.

The primary references are Charles, Montaraz, and Novotny. All of the differences between the primary references and the instant application presented above in the discussion of the 102 rejections are applicable for this discussion regarding obviousness, including that these references do not teach vaccine compositions comprising a recombinantly produced p68 antigen from *B. bronchiseptica* which lacks the signal sequence, and an adjuvant comprising saponin and a surfactant, nor do the primary references teach a method of protecting a dog against *B. bronchiseptica* comprising administering to the dog said vaccine.

The combining of the secondary references of Azko, Garcon, and Acree with the primary references does not overcome the deficiencies of the primary references. None of the references cited by the Examiner, alone or in combination, discloses a vaccine composition comprising a recombinantly produced p68 antigen for dogs which lacks the signal sequence, nor a vaccine composition for dogs containing the claimed adjuvant, nor a method of protecting dogs against *B. bronchiseptica* comprising administering to a dog said vaccine.

Akzo is directed to a respiratory disease vaccine for cats (See Abstract), and merely discloses vaccines for cats employing killed or inactivated *Bordetella bronchiseptica* or fimbriaem from a native organism, which is a preferred *Bordetella bronchiseptica* subunit antigen. This reference does not teach a vaccine composition comprising p68 antigen for dogs against *Bordetella bronchiseptica*, wherein the p68 antigen is produced recombinantly and lacks the signal sequence, in combination with a saponin adjuvant. There can be no expectation of success that the vaccine compositions disclosed in Akzo for cats could be used in or modified for the vaccine compositions for dogs of the instant application.

Garcon is directed to saponin and cholesterol as an adjuvant and *Bordetella bronchiseptica* antigen as possible application for the adjuvant. However, Applicants have discussed the issues regarding the cited references above and in the prior responses to Office Actions, and the mere teaching of saponin and cholesterol as a possible adjuvant for a *Bordetella*

bronchiseptica antigen does not ameliorate the deficiencies in the cited references. For example, as discussed above, a p68 antigen for pig is suggested to be a poor vaccine for dogs. There is simply no teaching or suggestion in the references that coupling saponin and/or cholesterol can cure such defect. Moreover, Garcon does not suggest that saponin and/or cholesterol can be used in combination with the p68 antigen.

Acree is directed to vaccine compositions containing inactivated canine coronavirus, alone or in combination with other viral antigens. This reference does not teach a vaccine composition comprising p68 antigen for dogs against *Bordetella bronchiseptica*, wherein the p68 antigen is produced recombinantly and lacks the signal sequence. There can be no expectation of success that the vaccine compositions disclosed in Acree could be used in or modified for the vaccine compositions for dogs of the instant application.

Claims 7-8 and 11-13 all depend from claim 1 or from claims that ultimately depend from Claim 1. They thereby embody each and every element of Claim 1 and further delineate the vaccine composition of Claim 1. Claim 10 comprises many of the elements of Claim 1. Accordingly, the subject matter of Claims 7-8 and 10-13 is not obvious in light of the cited references. Claim 6 is canceled rendering this rejection of this claim moot.

None of the references cited by the Examiner suggest Applicants' invention. In addition, Applicants respectfully submit that merely because the references can be combined, does not render the combination obvious. There is no indication in any of the references that would suggest that the references be combined with an expectation of success. Moreover, even when combined the references do not yield Applicants' invention. Accordingly, it is respectfully submitted that the claims are not rendered unpatentable over Charles et al, Montaraz et al, or by Novotny et al, in view of Akzo et al, and Garcon et al, and further in view of Acree et al. Thus, based on the remarks presented herein, the rejection of Claims 6-8 and 10-13 under 35 U.S.C. §103(a) is overcome. Because none of the references, alone or in combination, teaches Applicants' invention, withdrawal of the rejection is respectfully requested.

III. Conclusion

In view of the amendments and remarks made herein, Applicants respectfully submit that Claims 1, 3-5, 7-8, and 10-13 are in condition for allowance and request expedited notification of same.

Respectfully submitted,

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